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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/626,221	07/24/2003	Aaron J. Fleischman	CCF-5760	4555
26294 7590 05/17/2007 TAROLLI, SUNDHEIM, COVELL & TUMMINO L.L.P. 1300 EAST NINTH STREET, SUITE 1700 CLEVEVLAND, OH 44114				
			EXAMINER JUNG, UNSU	
			ART UNIT 1641	PAPER NUMBER
			MAIL DATE 05/17/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.		Applicant(s)	
	10/626,221		FLEISCHMAN ET AL.	
	Examiner		Art Unit	
	Unsu Jung		1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 February 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14-20, 34-52 and 55-60 is/are pending in the application.
- 4a) Of the above claim(s) 14-20, 34-44 and 46-49 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 45, 50-52 and 55-60 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The Examiner for the current application has been changed from Leon Y. Lum to Unsu Jung in Art Unit 1641. Any inquiry concerning this application should be directed to Unsu Jung, whose contact information is provided in the conclusion section of this Office Action.

Response to Amendment

2. Applicant's amendments to cancel claims 53, 54, and 61 and amend claims 45, 50, and 55 in the reply filed on February 22, 2007 have been acknowledged and entered.

It is further noted that the Remarks section of the reply filed on February 22, 2007 indicates that claim 52 has been amended, which is inconsistent with the Listing of Claims, which does not indicate that claim 52 has been amended.

3. Claims 14-20, 34-52, and 55-60 are pending, claims 14-20, 34-44, and 46-49 have been withdrawn from consideration, and claims 45, 50-52, and 55-60 are under consideration for their merits.

Rejections Withdrawn

2. Applicant's arguments, see p10, filed February 22, 2007, with respect to the rejection under 35 U.S.C. 112, second paragraph have been fully considered and are persuasive. The rejection of claims 45 and 50-61 under 35 U.S.C. 112,

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second paragraph has been withdrawn in light of amended claims 45, 55, and 60 in the reply filed on February 22, 2007.

3. Applicant's arguments, see p10, filed February 22, 2007, with respect to the rejection under 35 U.S.C. 102(e) as being anticipated by Jain et al. (US 2002/0081714 A1) have been fully considered and are persuasive. The rejection of claims 45 and 50-53 under 35 U.S.C. 102(e) as being anticipated by Jain et al. has been withdrawn in light of amended claim 45 and canceled claim 53 in the reply filed on February 22, 2007.

4. Applicant's arguments, see p13, filed February 22, 2007, with respect to the rejection on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 2, 7, and 15-21 of U.S. Patent No. 6,623,984 have been fully considered and are persuasive. The rejection of claims 45 and 50-52 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 2, 7, and 15-21 of U.S. Patent No. 6,623,984 has been withdrawn in light of amended claim 45 in the reply filed on February 22, 2007.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which

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said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 45 and 50-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jain et al. (US 2002/0081714 A1) in view of Zborowski et al. (*Cytometry*, 1996).

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Jain et al. teach a magnetic chip comprising a silicon substrate 25 (i.e. semi-conductor substrate) with magnetic islands 26 (i.e. at least one magnetic portion) thereon in a pattern that produces gaps in between the islands (i.e. comprises two magnetic pole pieces having an interpolar gap) such that magnetic beads can be trapped within the gaps by localized magnetic fields from the islands (i.e. magnetically manipulate magnetically susceptible particles into collection area). See page 6, section 0056; page 7, sections 0076-0077; page 10, section 0092; page 11, section 0113; page 12, section 0123; and Figures 1C-D. Jain et al. also teach a microfluidic assembly integrated with the chip and comprising a plurality of channels, sample inlet, and sample outlet ports (i.e. a fluid outlet), wherein the microfluidic assembly can be glass (i.e. transparent wall). See page 13, section 0136. Jain et al further teach on-chip photodetectors at the attachment sites of magnetic particles (i.e. at least one photosensitive sensor portion in physical communication with the fluid outlet; sensor portion being disposed within the interpolar gap) for detection of signals from beads, probes, and/or targets, wherein the detectors can be a photodiode, and wherein the signals can be fluorescence (i.e. light source that emits light of the predetermined wavelength to excite the one immunofluorescently labeled particles). See page 14, sections 0142-0143 and Figure 12. In addition, Jain et al. teach sample outlet ports (i.e. plurality of flow outlets) as disclosed above, and that the chip can comprise a plurality of arrays comprising the magnetic islands, each array being addressed by two crossed channels that can both introduce and remove reagents (i.e. provide an associated collection area within each of

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the plurality of flow outlets). See pages 13-14, sections 0133 and 0136-0137; and Figure 3.

In regards to claims 50-51, Jain et al. teach spin valve sensors that detect local magnetic fields by measuring the resistance in a strip of material while current is passed through it. See page 20, section 0202.

However, Jain et al. fails to teach that the plurality of flow outlets are arranged to run along mutually parallel paths and the at least one magnetic portion comprises two magnetic pole pieces, extended across the plurality of parallel paths as to magnetically manipulate magnetically susceptible particles within each of the plurality of flow outlets.

Zborowski et al. teach a ferrograph with two pole pieces of a permanent magnet that simultaneously provides a magnetic barrier for a plurality of channels, in order to separate five different cell samples simultaneously, which is significantly faster than using a single-channel design. See page 256, right column, 1st paragraph to page 257, left column, first paragraph; and Figure 1 and caption.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the apparatus of Jain et al. by substituting the array format with a ferrograph having two pole pieces of a permanent magnet that simultaneously provides a magnetic barrier for a plurality of channels, as taught by Zborowski et al., in order to separate five different cell samples simultaneously, which is significantly faster than using a single-channel design. Because the two pole pieces of Zborowski et al. are separate from the fluidic

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channels, they allow for more efficient separation of single-cell samples using individual channels, thereby providing the motivation to combine Jain et al and Zborowski et al references. In addition, one of ordinary skill in the art at the time of the invention would have had a reasonable expectation of success in including the two pole pieces of Zborowski et al as the only magnetic force on the microchip of Jain et al., since Jain et al. teach a linear setup of multiple magnetic localizations, and the pole pieces and separate channels of Zborowski et al. accommodate such a linear setup.

9. Claim 55-58 and 60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jain et al. (US 2002/0081714 A1) in view of Ellis et al. (US 4,091,280).

Jain et al. reference has been disclosed (see item 8 above), but fails to teach that the bioferrograph includes a light source that emits light of the predetermined wavelength to excite the one immunofluorescently labeled particles.

Ellis et al. teach the use of a single fiber optic cable for both the transmission and return of light signal, in order to reduce duplication and volume of material. See column 4, lines 5-21.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the apparatus of Jain et al. with a single fiber optic cable having the capability of conveying both transmitted and return light signals, as taught by Ellis et al., in order to reduce duplication and volume of material. The

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advantage of using minimal material, especially for the small arrays taught by Jain et al., provides the motivation to combine the teachings of Jain et al and Ellis et al. In addition, one of ordinary skill in the art at the time of the invention would have had a reasonable expectation of success in applying the single fiber optic cable of Ellis et al. to the apparatus of Jain et al, since Jain et al. teach photodiode detectors, and the fiber optic cable of Ellis et al. is capable of attaching to photodiodes. See column 3, line 65.

In regards to claim 61, Jain et al. teach data processing using image processing tools and software. See page 7, section 0076

10. Claim 59 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jain et al. (US 2002/0081714 A1) in view of Ellis et al. (US 4,091,280) as applied to claim 55 above, and further in view of Zborowski et al. (*Cytometry*, 1996).

Jain et al. and Ellis et al. references have been disclosed above (see item 9 above), but fail to teach that the plurality of flow outlets are arranged to run along mutually parallel paths and the at least one magnetic portion comprises two magnetic pole pieces, extended across the plurality of parallel paths as to magnetically manipulate magnetically susceptible particles within each of the plurality of flow outlets.

Zborowski et al. teach a ferrograph with two pole pieces of a permanent magnet that simultaneously provides a magnetic barrier for a plurality of channels, in order to separate five difference cell samples simultaneously, which is significantly faster than using a single-channel design. See page 256, right

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column, 1st paragraph to page 257, left column, first paragraph; and Figure 1 and caption.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the apparatus of Jain et al. and Ellis et al. by substituting the array format with a ferrograph having two pole pieces of a permanent magnet that simultaneously provides a magnetic barrier for a plurality of channels, as taught by Zborowski et al., in order to separate five different cell samples simultaneously, which is significantly faster than using a single-channel design. Because the two pole pieces of Zborowski et al. are separate from the fluidic channels, they allow for more efficient separation of single-cell samples using individual channels, thereby providing the motivation to combine Zborowski et al. with Jain et al. and Ellis et al. references. In addition, one of ordinary skill in the art at the time of the invention would have had a reasonable expectation of success in including the two pole pieces of Zborowski et al. as the only magnetic force on the microchip of Jain et al. and Ellis et al., since Jain et al. and Ellis et al. teach a linear setup of multiple magnetic localizations, and the pole pieces and separate channels of Zborowski et al. accommodate such a linear setup.

A typo has been noted in the Office Action dated October 19, 2006, where "Jain et al. in view of Walt et al." on pp8-9 (see item 14) should be corrected to "Jain et al. in view of Ellis et al." The correction has been made in this Office Action as indicated by underline portions as set forth above.

Response to Arguments

11. Applicant's arguments with respect to claims 45 and 50-52 have been considered but are moot in view of the new ground(s) of rejection. However, the following arguments have been addressed as they may also be applied to the current rejections.

Applicant's argument that the teachings of Zborowski et al. could not be incorporated into the system of Jain et al. because magnetic particles would be trapped between the two pole pieces and there would be no ordering force in the opposite direction such that ordered array could be achieved is not found persuasive in view of previously stated grounds of rejection. As stated in the previous Office Action dated October 19, 2006, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the apparatus of Jain et al. by substituting the array format with a ferrograph having two pole pieces of a permanent magnet that simultaneously provides a magnetic barrier for a plurality of channels, as taught by Zborowski et al. Therefore, Applicant's argument that magnetic particles would be trapped between the two pole pieces and there would be no ordering force in the opposite direction such that ordered array could be achieved is irrelevant as the array format of Jain et al. is being substituted by the ferrograph of Zborowski et al. Further, Applicant's argument is not commensurate with the scope of the instant claims.

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12. Applicant's arguments filed on February 22, 2007 with respect to claims 55-60 have been fully considered but they are not persuasive in view of previously stated grounds of rejection.

With respect to Applicant's argument regarding the "computerized quantification system," the functional recitation that "quantification system capable of correlating the detected luminosity at each collection area with a quantity of immunofluorescently labeled particles" has not been given patentable weight because it is narrative in form. In order to be given patentable weight, a functional recitation must be expressed as a "means" for performing the specified function, as set forth in 35 U.S.C. 112, sixth paragraph, and must be supported by recitation in the claim of sufficient structure to warrant the presence of the functional language. *In re Fuller*, 1929 C.D. 172; 388 O.G. 279. It has been held that the term "integral" is sufficiently broad to embrace the constructions united by such means as fastening and welding. *In re Hotte*, 177 USPQ 326, 328 (CCPA 1973). Further, Jain et al. discloses a computerized quantification system capable of correlating the detected luminosity at each collection area with a quantity of immunofluorescently labeled particles as the computerized quantification system of Jain et al. can detect the presence of single magnetic particle based on the detected luminosity at each collection as admitted by the Applicant (p13).

13. Since the prior art fulfills all the limitations currently recited in the claims, the invention as currently recited would read upon the prior art.

Conclusion

14. No claim is allowed.

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Unsu Jung whose telephone number is 571-272-8506. The examiner can normally be reached on M-F: 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax

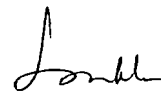
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phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Unsu Jung, Ph.D.
Patent Examiner
Art Unit 1641



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